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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier	<i>J. M. [signature]</i>

Food and Drug Administration

[Docket No. 98 D-0514]

Draft Guidance for Industry on ANDA's: Impurities in Drug Substances; Availability; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until November 23, 1998, the comment period for the draft guidance for industry entitled ‘ ‘ANDA's: Impurities in Drug Substances. ’ FDA published a notice of availability of the draft guidance in the Federal Register of July 24, 1998 (63 FR 39880). FDA is taking this action in response to several requests for an extension.

DATES: Written comments on the draft guidance may be submitted by November 23, 1998. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of the draft guidance are available on the Internet at ‘ ‘[http://www.fda.gov/cder/guidance/index .htm](http://www.fda.gov/cder/guidance/index.htm)’. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, **Rockville**, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, **Rockville**, MD 20852. Comments are to be identified with the docket number found in brackets in the heading of this document.

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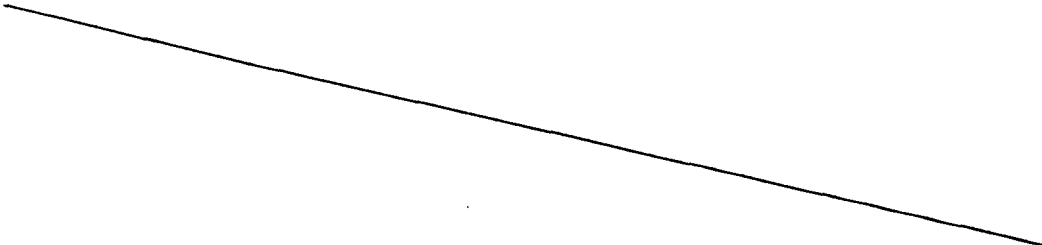
FOR FURTHER INFORMATION CONTACT: Robert W. Trimmer, Office of Generic Drugs, Center for Drug Evaluation and Research (HFD-625), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855-2737, 301-827-5848.

SUPPLEMENTARY INFORMATION: In the Federal Register of July 24, 1998 (63 FR 39880), FDA published a notice announcing the availability of a draft guidance for industry entitled ‘ ‘ANDA’s: Impurities in Drug Substances.’ ’ The draft guidance provides recommendations for including information in abbreviated new drug applications and supporting drug master files on the content and qualification of impurities in drug substances produced by chemical syntheses for both monograph and nonmonograph drug substances. Interested persons were given until September 22, 1998, to submit written comments on the draft guidance.

On August 4, 1998, FDA received a letter from Perrigo requesting that the agency extend the comment period on the draft guidance 120 days. On August 10, 1998, FDA received a letter from the National Association of Pharmaceutical Manufacturers requesting that the agency extend the comment period on the draft guidance 60 days. On September 4, 1998, FDA received a letter from the Generic Pharmaceutical Industry Association requesting that the agency extend the comment period on the draft guidance 60 days.

This draft guidance is complex and introduces a number of new issues. Therefore, the agency has decided to reopen the comment period on the draft guidance until November 23, 1998, to allow the public more time to review and comment on its contents.

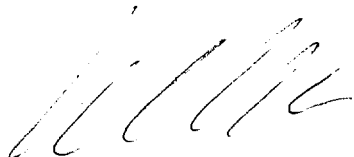
Interested persons may, on or before November 23, 1998, submit to the Dockets Management Branch (address above) written comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance



and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 8, 1998

October 8, 1998



William K. Hubbard
Associate Commissioner for Policy Coordination

[FR Dec. 98-???? Filed ??-??-98; 8:45 am]

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